

(12) **United States Patent**
Sandhu

(10) **Patent No.:** **US 9,084,670 B2**
(45) **Date of Patent:** ***Jul. 21, 2015**

(54) **CERVICAL IMMOBILIZATION COLLAR WITH ARTERIAL COOLING ELEMENTS AND METHOD OF USING THE SAME**

USPC 602/17-19; 128/DIG. 23
See application file for complete search history.

(75) Inventor: **Aqeel A. Sandhu**, North Canton, OH (US)

(56) **References Cited**

U.S. PATENT DOCUMENTS

(73) Assignee: **Cryothermic Systems, Inc.**, Broadview Heights, OH (US)

2,801,630 A 8/1957 Moore
2,911,970 A 11/1959 Bartels
3,042,026 A 7/1962 Monfardini

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(Continued)

This patent is subject to a terminal disclaimer.

FOREIGN PATENT DOCUMENTS

WO 0007529 2/2000

OTHER PUBLICATIONS

(21) Appl. No.: **13/606,294**

CFR—Code of Federal Regulations Title 21, vol. 8, revised as of Apr. 1, 2013 Food and Drugs, Chapter I—Food and Drug Administration Department of Health and Human Services—Subchapter H—Medical Devices.

(22) Filed: **Sep. 7, 2012**

(65) **Prior Publication Data**

US 2013/0245407 A1 Sep. 19, 2013

(Continued)

Related U.S. Application Data

(63) Continuation-in-part of application No. 12/913,215, filed on Oct. 27, 2010, now Pat. No. 8,262,597, and a continuation-in-part of application No. 12/429,663, filed on Apr. 24, 2009, now Pat. No. 7,846,118, and a continuation of application No. 11/162,922, filed on Sep. 28, 2005, now abandoned.

Primary Examiner — Michael Brown

(74) *Attorney, Agent, or Firm* — Benesch, Friedlander, Coplan & Aronoff, LLP

(51) **Int. Cl.**

A61F 5/00 (2006.01)
A61F 5/055 (2006.01)
A61B 5/1455 (2006.01)
A61B 5/0205 (2006.01)

(57)

ABSTRACT

A method for selective cooling of the brain of a patient includes providing a cervical immobilization collar, the collar including a substantially annular support structure having an extended axial length, an anterior opening, and a securing member capable of substantially covering the anterior opening. The method also includes applying the cervical immobilization collar to the patient, placing a first cooling element within the anterior opening of the substantially annular support structure, and securing the first cooling element within the anterior opening.

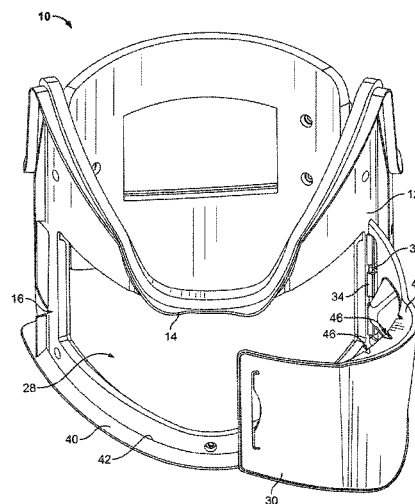
(52) **U.S. Cl.**

CPC **A61F 5/055** (2013.01); **A61B 5/02055** (2013.01); **A61B 5/14551** (2013.01)

(58) **Field of Classification Search**

CPC . A61F 5/055; A61B 5/02055; A61B 5/14551

20 Claims, 7 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

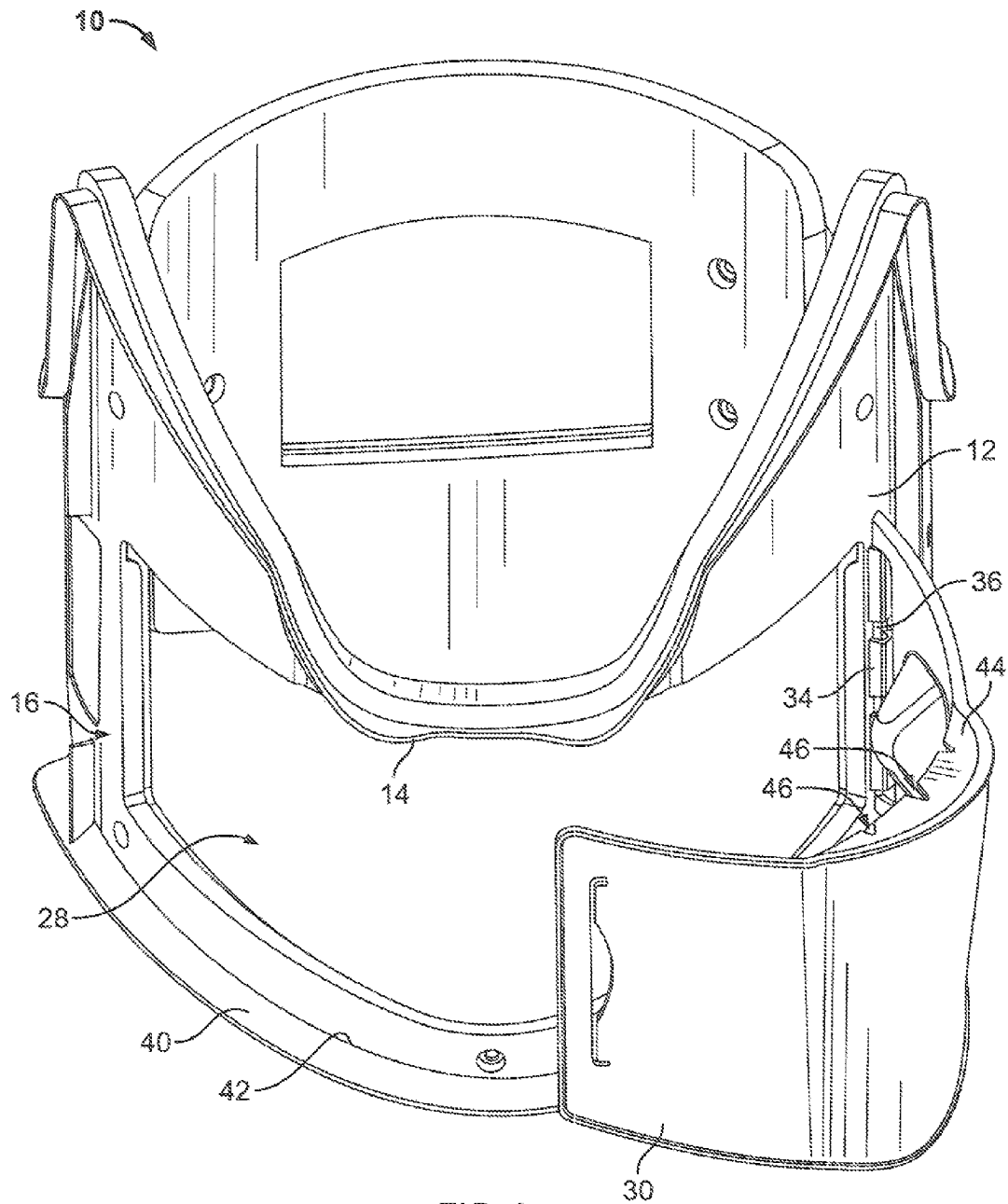
D203,018 S 11/1965 Helferich
 D292,768 S 11/1965 Marks
 D213,742 S 4/1969 Bond
 4,137,769 A 2/1979 Parker
 4,325,254 A 4/1982 Svacina et al.
 4,427,010 A 1/1984 Marx
 4,745,922 A * 5/1988 Taylor 607/104
 4,783,866 A 11/1988 Simmons et al.
 4,827,915 A 5/1989 Gorsen
 4,832,030 A 5/1989 De Canto
 5,005,374 A 4/1991 Spitler
 5,007,416 A 4/1991 Burns et al.
 5,010,877 A 4/1991 Druskoczi
 5,300,105 A 4/1994 Owens
 1,525,771 A 2/1995 Falconer
 5,415,624 A 5/1995 Williams
 RE35,290 E 7/1996 Druskoczi
 5,575,812 A 11/1996 Owens
 5,622,529 A 4/1997 Calabrese
 5,626,151 A 5/1997 Linden
 5,795,315 A 8/1998 Traut et al.
 5,797,713 A 8/1998 Tweardy et al.
 5,916,242 A 6/1999 Schwartz
 6,030,412 A 2/2000 Klatz et al.
 6,126,680 A 10/2000 Wass
 6,231,535 B1 5/2001 Mainiero et al.
 6,416,532 B1 7/2002 Fallik

6,494,854 B1 12/2002 Visness et al.
 6,497,721 B2 12/2002 Ginsburg et al.
 6,508,831 B1 1/2003 Kushnir
 6,527,798 B2 3/2003 Ginsburg et al.
 6,599,312 B2 * 7/2003 Dobak, III 607/105
 6,620,188 B1 9/2003 Ginsburg et al.
 6,682,552 B2 * 1/2004 Ramsden et al. 607/109
 6,865,825 B2 3/2005 Bailey, Sr. et al.
 7,090,652 B2 8/2006 Santelli, Jr.
 7,361,186 B2 4/2008 Voorhees et al.
 D616,997 S 6/2010 Thorgilsdottir et al.
 7,846,118 B2 12/2010 Sandhu
 8,267,878 B2 9/2012 Sandhu et al.
 2002/0103520 A1 * 8/2002 Latham 607/108
 2003/0055473 A1 3/2003 Ramsden et al.

OTHER PUBLICATIONS

Pre-Hospital Cervical Spinal Immobilization of Following Trauma, the Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons. Sep. 20, 2001.
 International Search Report and Written Opinion for PCT/US2013/058457, mailed Dec. 16, 2013.
 International Search Report and Written Opinion for PCT/US2011-058090, mailed May 4, 2012.
 International Search Report for PCT/US2005/035095, mailed Jun. 30, 2006.

* cited by examiner



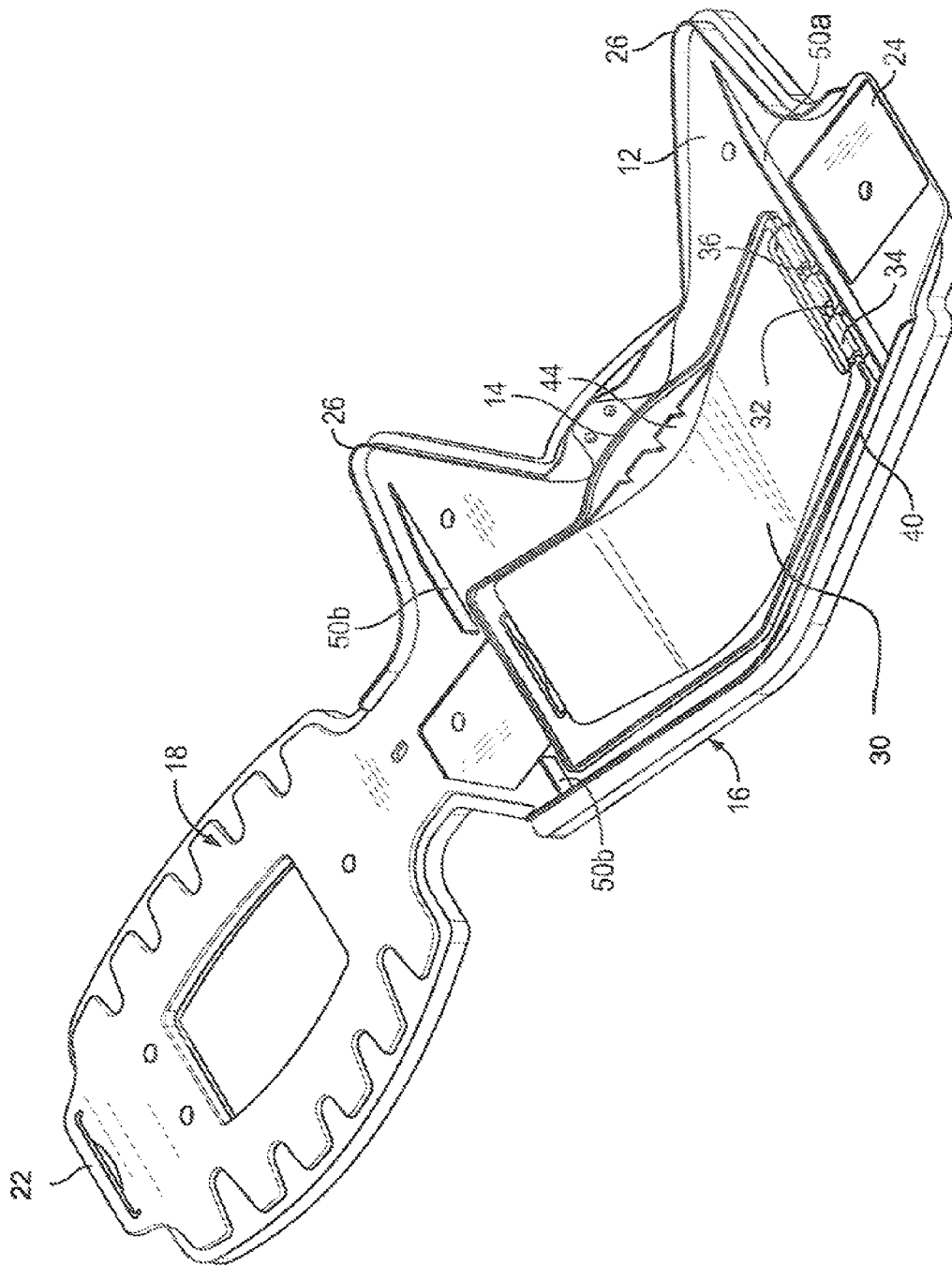
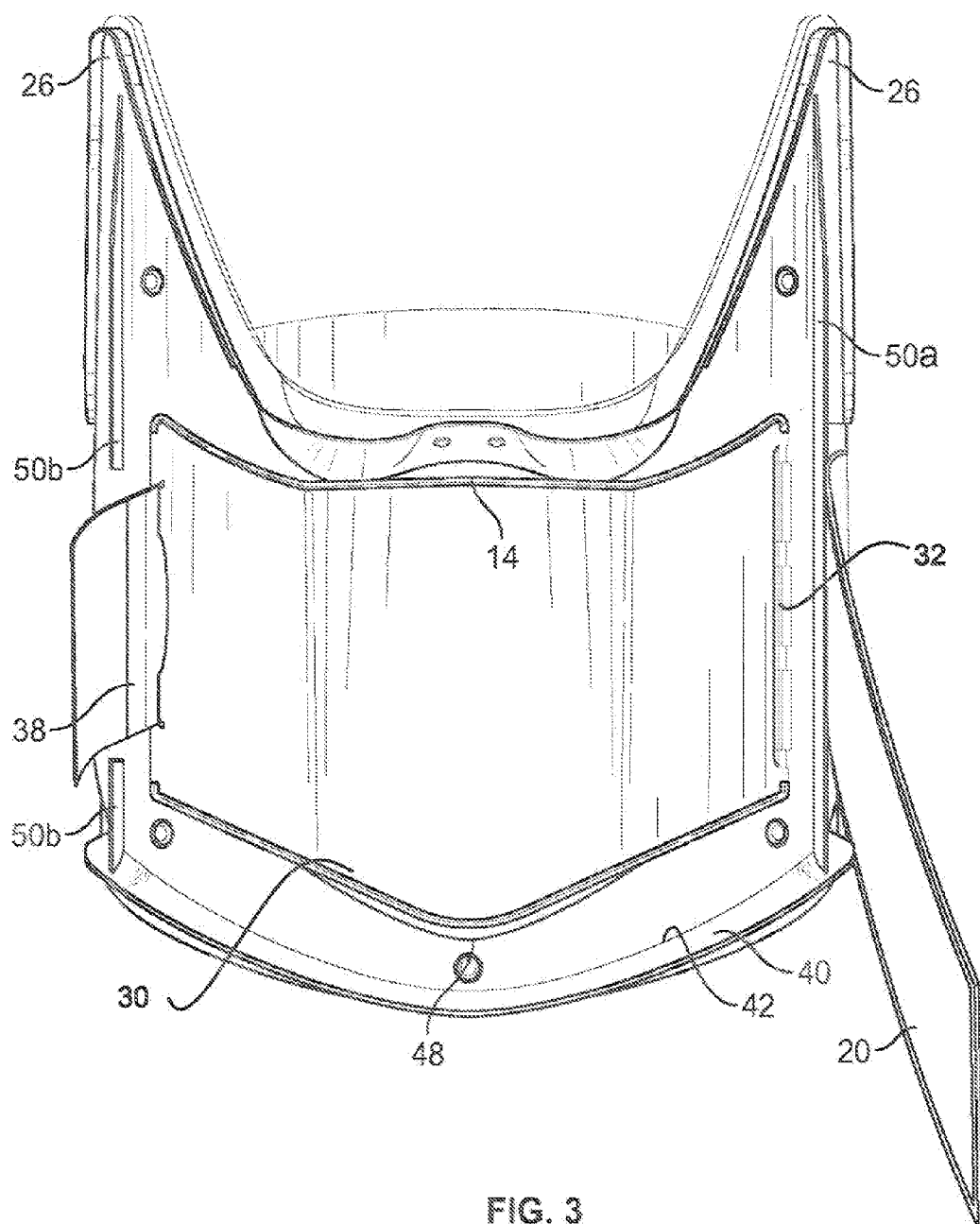


FIG. 2



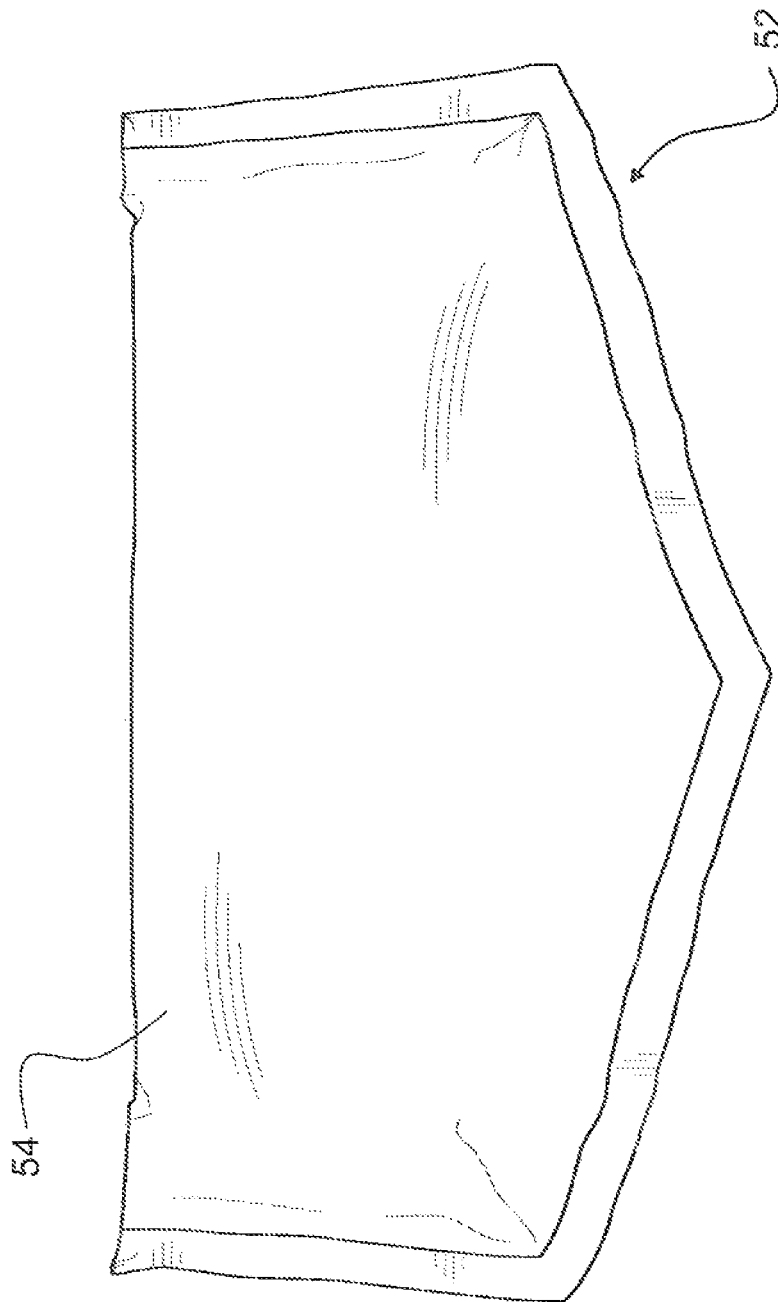


FIG. 4

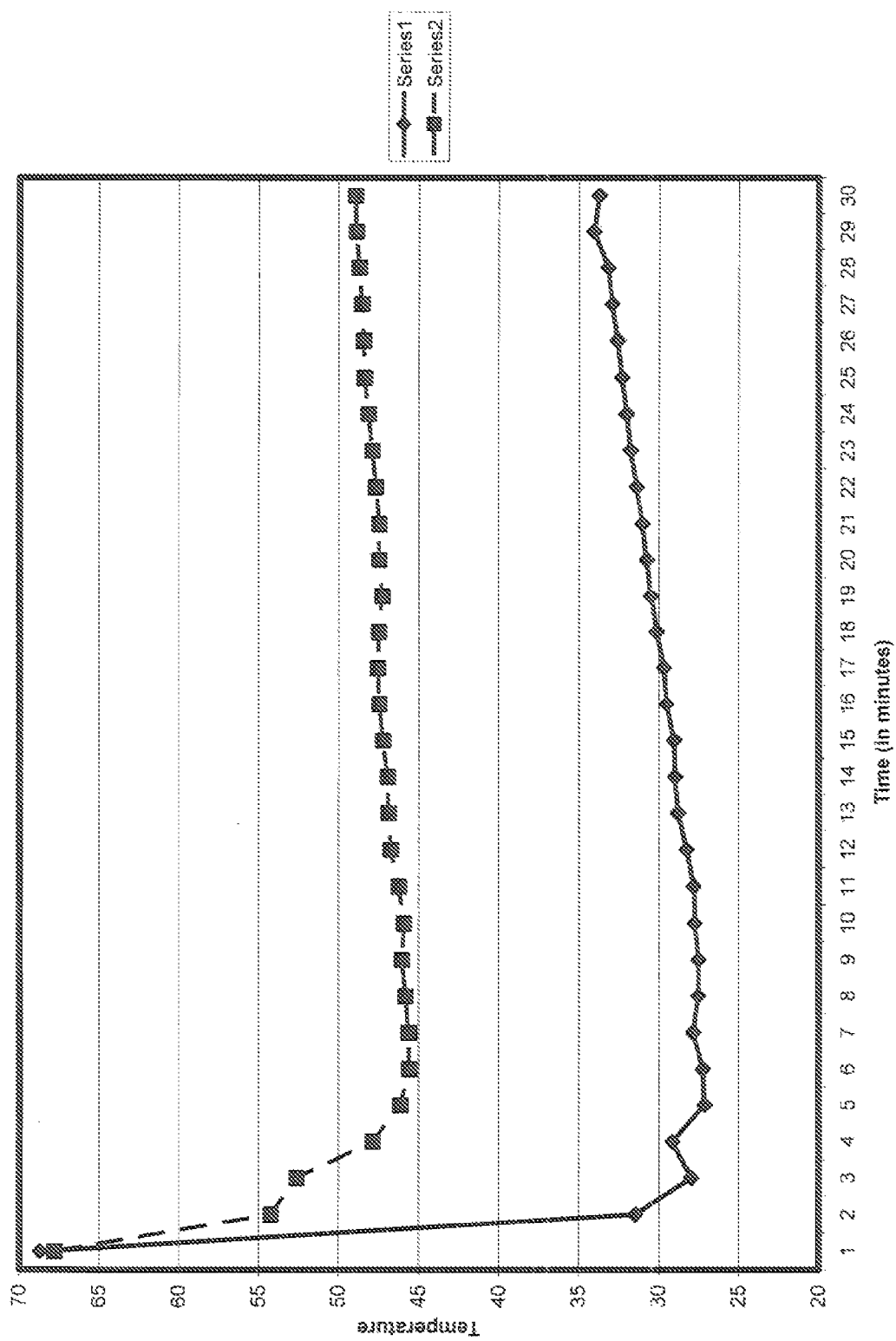


FIG. 5

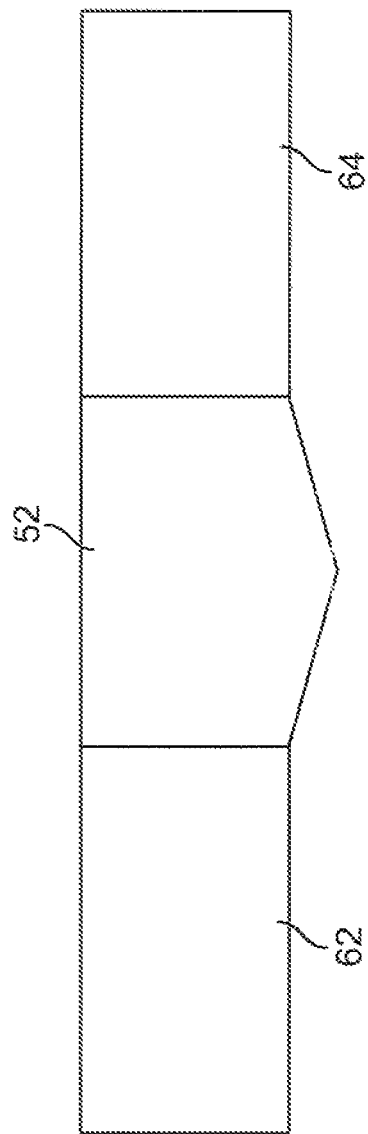


FIG. 6

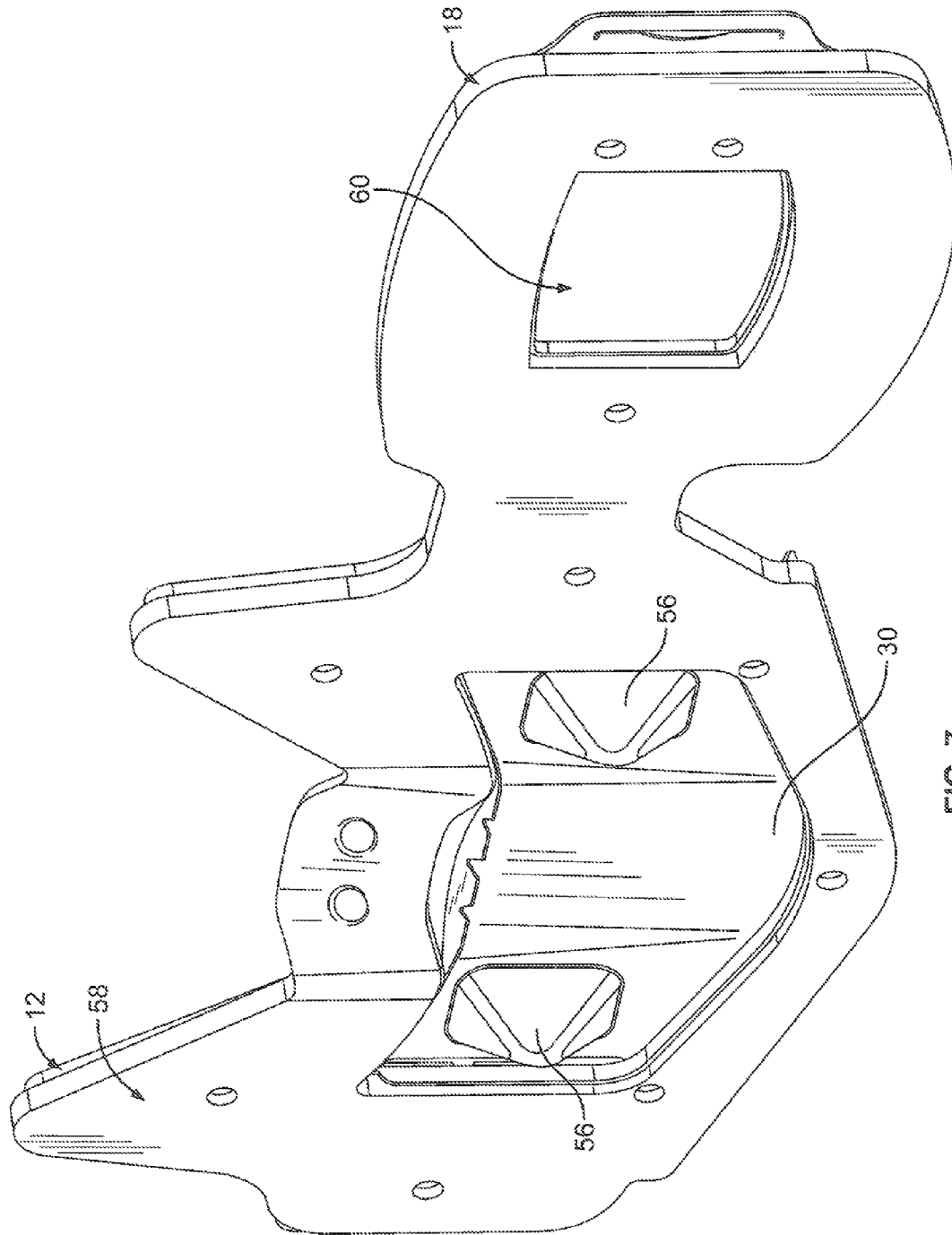


FIG. 7

1

CERVICAL IMMOBILIZATION COLLAR WITH ARTERIAL COOLING ELEMENTS AND METHOD OF USING THE SAME

This application is a continuation-in-part of U.S. patent application Ser. No. 12/913,215, filed on Oct. 27, 2010, which is a continuation-in-part of U.S. Pat. No. 7,846,118, issued on Dec. 7, 2010 which is a continuation of U.S. patent application Ser. No. 11/162,922, filed Sep. 28, 2005 (now abandoned).

BACKGROUND OF INVENTION

The invention integrates technologies relating to cervical immobilization and to therapeutic induction of mild cerebral hypothermia by transcutaneous cooling of oxygenated blood flowing through carotid arteries.

Cervical immobilization collars are often used by first-responders, such as EMTs, to stabilize the neck, head, and spine of a patient immediately after a trauma has occurred. While this procedure is generally effective to prevent further injury, it is helpful to begin to treat the patient's trauma before reaching the hospital. One method of treatment may include cooling the patient's brain. Brain cooling, i.e., reducing brain temperatures by as little as one or two degrees Celsius, produces a neuroprotective effect against deleterious responses associated with brain injuries. This mild cerebral hypothermia inhibits the release of neuroexcitatory amino acids (e.g., aspartate and glutamine), thereby interrupting the cascading effects of the inflammatory response. The neuroprotective effect is most pronounced if brain cooling is affected as soon as possible following an injury.

Protocols for first responders generally do not incorporate effective procedures for initiating brain cooling. For example, it is known to apply cold packs to the patient's body, to the groin, skull, and under the arm. This type of cooling, however, imparts systemic cooling, rather than selective cooling, and may not effectively drop the temperature of the patient's brain.

SUMMARY OF INVENTION

A method for selective cooling of the brain of a patient includes the steps of providing a cervical immobilization collar, the collar including a substantially annular support structure having an extended axial length, an anterior opening, and a securing member capable of substantially covering the anterior opening, applying the cervical immobilization collar to the patient, placing a first cooling element within the anterior opening of the substantially annular support structure, and securing the first cooling element within the anterior opening. The method may also include providing a securing member with at least one pressure member capable of imparting pressure against the first cooling element and replacing the first cooling element with a second cooling element within about 15 to about 30 minutes of the time the first cooling element was placed within the anterior opening.

In another embodiment, the method for selectively cooling the brain of a patient may include providing a cervical immobilization collar comprising a substantially annular support structure with an extended axial length and an anterior opening, applying the cervical immobilization collar to the patient, providing at least one cooling element, placing the at least one cooling element within the anterior opening of the substantially annular support structure, and securing the at least one first cooling element within the anterior opening; wherein the

2

cervical immobilization collar is capable of securing the at least one cooling element within the anterior opening.

DESCRIPTION OF THE DRAWING FIGURES

FIG. 1 is perspective view of a cervical immobilization collar.

FIG. 2 is a top view of a the cervical immobilization collar.

FIG. 3 is a front view of the cervical immobilization collar.

FIG. 4 is a top view of a cooling element for use in the cervical immobilization collar.

FIG. 5 is a graphical representation of the temperatures obtained by the activated cooling element over time.

FIG. 6 is a top view of a cooling element for use with a neck band.

FIG. 7 is a rear view of the cervical immobilization collar.

DETAILED DESCRIPTION

A cervical immobilization collar **10** may be used to stabilize a patient's spine, neck, and head immediately following a trauma. As shown in FIGS. 1-3 and 7, a cervical immobilization collar **10** for use with cooling elements may generally include a substantially annular support structure **12** with an anterior portion **16**, which wraps around the front of the patient's neck, and a posterior portion **18**, which wraps around the back of the patient's neck. The anterior portion **16** and the posterior portion **18** may be formed of a single piece of material. In an alternative embodiment, the anterior portion **16** and posterior portion **18** may be separate components connected on one or both sides of the neck by a joint or by an attachment mechanism, such as a hook and loop fastener. The substantially annular support structure **12** can be formed (preferably by pour or injection molding) from a variety of materials including plastics, polymers, or carbon or poly-paraphenylene terephthalamide fiber. In one embodiment, the annular support structure **12** comprises SCLAIR® 2712 high density polyethylene, manufactured by NOVA Chemicals supplied by Entec Polymers.

Referring to FIGS. 2 and 3, a hook and loop fastener strap **20** (as shown in FIG. 3) extends from a distal end **22** of the posterior portion **18** for releasably engaging a mating hook-and-loop fastener patch (not shown) mounted on the proximal end **24** of the anterior portion **16** of the substantially annular support structure **12**.

The anterior portion **16** of the substantially annular support structure **12** may include cheek support structures **26**. The cheek support structures **26** may generally extend vertically from the either side of the chin rest **14** and are configured to cover the area generally associated with the patient's cheek. The cheek support structures **26** may be used to prevent significant rotational or lateral movement of the patient's head. The cheek support structures **26** may be formed integrally as a part of the substantially annular support structure **12**, as shown, or may be formed separately and mounted on to the substantially annular support structure **12** with an appropriate adhesive or attachment mechanism. In another embodiment (not shown), the annular support structure **12** may not include cheek supports.

Referring again to FIG. 1, the cervical immobilization collar **10** also includes an anterior opening **28** in the anterior portion **16** of the substantially annular support structure **12**. The anterior opening **28** is defined by the frame of the substantially annular support structure **12**. Traditional neck braces may include an opening in the front of the brace, but the opening is generally only large enough to provide access to the patient's trachea in a case of a blocked airway. Alter-

3

natively, the anterior opening 28 in the cervical immobilization collar 10 is designed to traverse the front of the patient's neck, exposing both of the patient's carotid artery regions, as opposed to only the trachea region.

As shown in FIG. 2, the cervical immobilization collar 10 may also include a securing member 30, such as a Velcro® band or a door, that is capable of substantially covering the anterior opening 28. In one embodiment, the securing member 30 is a door with a first edge portion attached to the frame of the substantially annular support structure 12 at or about one end, or a first edge portion, of the anterior opening 28 with a hinge 32, or other appropriate fastening mechanism. It is also contemplated that the cervical immobilization collar 10 may not include a separate securing member 30.

As shown in FIGS. 1 and 2, in one embodiment, a two part hinge may be used to secure the securing member 30 to the substantially annular support structure 12. In this embodiment, the first part of the hinge 34 may be integrally formed as part of the frame of the substantially annular support structure 12. Specifically, the first part of the hinge 34 may comprise from one, and preferably three, elastically deformable flanges. The second part of the hinge 36 may be integrally formed as part of the first edge portion of the securing member 30. The second part of the hinge 36 may be snapped in to place within the first part of the hinge 34 by deforming the flanges. Once snapped in place, the second part of the hinge 36 is rotatable within the flanges of the first part of the hinge 34 so that the securing member 30 may be opened and closed, relative to the frame of the substantially annular support structure 12. In another embodiment, the hinge 32 may be a living hinge (not shown) that is integrally formed between the first edge portion of the securing member 30 and the frame of the annular support structure 12.

A second edge portion of the securing member 30 may be fastened to the frame of the substantially annular support structure 12 at a second edge portion of the anterior opening 28 with second hook and loop fastener strap 38 (shown in FIG. 3), which extends from the second edge portion of the securing member 30, and a mating hook-and-loop fastener patch (not shown) mounted on or about the frame of the substantially annular support structure 12 at or near the second edge portion of the anterior opening 28. The closure may also be effectuated with a snap fit mechanism; pressure fit mechanisms, buttons, latches, adhesives, or other appropriate fastening mechanism.

As discussed above, the anterior opening 28 extends substantially across the majority of the anterior portion 16 of the substantially annular support structure 12. The immobilization collar 10, however, must be strong enough to support the patient's neck and prevent flexion, or movement in which the chin is lowered down toward the chest. In traditional neck braces, this strength is provided by the structural material between the chin rest and the bottom of the brace. However, the large anterior opening 28, and lack of structural material between the chin rest 14 and the bottom of the collar 10, may compromise the strength and support provided by the immobilization collar 10, particularly in the vertical plane. Thus, the patient may be able to move their head up and down, even when wearing the collar 10. In order to provide the needed support and, thus, significantly hinder the patient's ability to move their head up and down, support members are built into the substantially annular support structure 12.

As shown in FIG. 1, a horizontally protruding ledge 40 may extend perpendicularly from a bottom edge 42 of the anterior portion of the annular support structure 12. In one embodiment, the ledge 40 may be integrally formed as part of the annular support structure 12 and may preferably extend

4

across the entire anterior portion 16 of the frame of the substantially annular support structure 12. Similarly, the securing member 30 may include a shelf 44 that extends perpendicularly from the top edge of the securing member 30, as shown in FIG. 1, inward toward the patient's body. The shelf 44 may be integrally formed as part of the securing member 30. The shelf 44 may also include gaps 46 that allow the shelf 44, as part of the securing member 30, to bend during use.

When the securing member 30 is placed over the anterior opening 28, as shown in FIG. 3, and the patient attempts to move their head down, the bottom 48 of the securing member 30 abuts the ledge 40. Similarly, the shelf 44 (shown in FIGS. 1 and 2) on the securing member 30 will abut the bottom of the chin rest 14, hindering the downward movement and effectively using the securing member 30 as the structural material between the chin rest 14 and the bottom of the collar 10.

Lateral ribs 50a and 50b may be included as well to add structural support to the anterior portion of the annular support structure 12. As shown in FIGS. 2 and 3, the lateral ribs 50a and 50b are integrally formed on the exterior surface of the annular support structure 12 and extend from under the apex of the cheek support structures 26 and abut the ledge 40. As shown in FIG. 3, lateral rib 50b may be formed of two separate pieces, a first extending from the apex of the cheek support 26 and a second extending up from the ledge 40, to accommodate the hook and loop fastener on the securing member 30.

Alternatively, the collar 10 may be comprised of material that is strong enough to prevent flexation. In one embodiment, the collar 10 may be made of high-density polyethylene (HDPE) or low-density polyethylene (LDPE). Suitable polyethylene material is commercially available from Laszery Technologies, Inc. in North Royalton, Ohio. In this embodiment, it would be unnecessary to include the lateral ribs 50a and 50b or other structural supports in the collar 10 to prevent the anterior opening 28 from collapsing when the collar 10 is in use.

The cervical immobilization collar 10 may be used in conjunction with a at least one cooling element 52. The cooling element 52, shown in FIG. 4, may have a shape that is substantially similar, or slightly larger, than the shape of the anterior opening 28, although the shape may take other forms. The cooling element 52 may include a body-facing panel 54 and an outward-facing panel (now shown) that are secured at their edges with a heat-activated adhesive seal or other appropriate sealing mechanism. In one embodiment, the body-facing panel 54 and the outward-facing panel may be formed of one sheet of material that is folded in half and sealed at its open edges or two sheets of material that are sealed along all of their edges. The cooling element 52 may include cooling material that produces endothermic reactions, previously chilled gels, or other materials having the capacity to absorb heat. Once the components of the endothermic packs are mixed or otherwise activated, the cooling element 52 is preferably put into immediate use.

In one embodiment, the panels may include a lining layer, that covers at least the body-facing panel 54 of the cooling element 52 that comes into contact with the patient's neck. In one embodiment, the lining layer substantially covers the body-facing panel 54 of the cooling element 52. In another embodiment, both panels of the cooling element 52 are covered with the lining layer. The lining layer may be made of fabric, for example a non-woven material, and may generally be used to provide comfort and prevent skin irritation, skin degradation, and potential frostbite. The lining layer may be adhered to the panels or may be detachable.

5

In one embodiment, the panels of the cooling element include a lining layer comprised of a non-woven material that is adhered to one or both of the panels. The panels may be comprised of a film-like material. In one example, a 0.007 mm non-woven lining layer is laminated onto a 2.5 mm linear low density white polyethylene film to form both panels of the cooling element 52. The water permeability of the panels may be 0.41 grams/100sq in/24 hrs and the oxygen gas permeability may be less than 9.0 cc/100 sq in/24 hrs.

In this embodiment, the cooling element 52 may be approximately 10 to about 12 inches long and may include about 90 to about 110 g urea, about 45 to about 55 g Carbamakoool™, and water. In another embodiment, the cooling element 52 may be about 10 inches long and include about 100 g urea, about 50 g Carbamakoool™, and water. In another embodiment, the cooling element 36 may be about 11 inches long and include about 110 g urea, about 55 g Carbamakoool™, and water. In these embodiments, the crystal like urea and Carbamakoool™ are mixed together and sealed between the panels of the cooling element 52. In this embodiment, the cooling element 52 also includes a liquid-filled, preferably water, frangible packet (not shown). The liquid-filled packet is also sealed between the panels of the cooling element 52. To activate the cooling element 52, a user, applying pressure to the cooling element 52, ruptures the packet, which wets the urea and Carbamakoool™. The user then shakes the cooling element 52 to mix the ingredients and initiate an endothermic reaction.

The cooling material in the cooling element preferably reaches a temperature of 20° F. to 45° F., desirably 25° F. to 35° F., within a minute of activation, and maintains the temperature for a period of about 10 to about 30 minutes, preferably from about 15 to about 20 minutes. Suitable cooling materials for the cooling elements 52 are available from Nortech Labs, 125 Sherwood Avenue Farmingdale, N.Y. 11735.

Unlike known cold packs, which come with instructions directing the users not to place cold pack directly on the patient's skin, the cooling element 52, including a fabric lining layer laminated to the panels, allows the user to place the cooling element 52 directly on the skin of the patient for up to 20 to 30 minutes. Moreover, laminating, or otherwise adhering, the fabric lining layer to the panels film prevents the cooling element 52 from slipping out of place and away from the carotid arteries when in use against the patient's neck.

The reduced temperature produced by the mixture of urea, Carbamakoool™, and water is measured on the outer surface of the cooling element 52. In other words, the temperature that the patient comes in contact with is measured to evaluate the amount of heat extraction effectuated by the cooling element 52. Using a fabric lining layer, however, insulates the cooling element 52, and therefore the internal capacity of the cooling element 52 and the amount of urea and Carbamakoool™ used therein is important to properly extract heat from the patient's carotid arteries.

EXAMPLE

One lot of cooling elements 52, samples A-E, were tested. Each sample was 10 inches in length and included 100 g urea, and 50 g Carbamakoool™. Both panels of samples A-E were comprised of a 0.007 mm non-woven lining layer laminated onto a 2.5 mm linear low density white polyethylene film.

The samples were activated by squeezing the samples to break a water-filled frangible packet that was sealed within the panels, then shaking each sample ten (10) times. The samples were folded and inserted into 16 oz Styrofoam cups.

6

The ambient temperature, 68.7° F., was recorded and thermocouples were placed in the fold of each cooling element about one inch from the bottom of the cups. Temperature readings were recorded once a minute with the last recording made after 30 minutes. Each cooling element was re-shaken after a two minute elapsed time. The results are shown in Table I below:

TABLE I

Time (min)	Sample A	Sample B	Sample C	Sample D	Sample E
1	68.7	68.7	68.7	68.7	68.7
2	42.0	27.3	30.0	30.7	27.3
3	35.0	24.8	28.5	27.0	24.6
4	34.9	24.0	27.1	35.7	24.1
5	35.1	23.8	26.9	25.6	24.3
6	35.3	23.7	26.9	25.8	24.5
7	35.5	23.8	29.9	25.4	24.7
8	35.7	24.0	27.2	25.5	25.2
9	35.9	24.2	27.3	26.1	24.1
10	36.1	24.5	27.9	25.9	24.4
11	36.2	24.9	28.1	25.0	24.9
12	36.4	25.2	28.5	26.2	25.0
13	36.6	25.5	29.9	26.7	25.3
14	36.8	25.8	29.4	27.0	25.9
15	37.0	26.2	29.7	27.3	25.0
16	37.1	26.5	30.0	27.7	26.3
17	37.3	26.0	30.5	28.1	26.5
18	37.5	27.1	30.8	28.5	26.8
19	37.7	27.5	31.3	28.9	27.1
20	37.9	27.8	31.6	29.3	27.2
21	38.1	28.1	31.9	29.6	27.5
22	38.3	28.5	32.3	30.0	27.9
23	38.6	28.7	32.7	30.5	28.4
24	38.8	29.1	32.9	30.6	28.7
25	39.0	29.5	33.3	30.8	28.9
26	39.2	29.8	33.5	31.2	29.1
27	39.4	30.1	34.1	31.5	29.5
28	39.5	30.5	34.4	31.7	29.8
29	39.8	30.8	37.7	32.0	30.0
30	40.0	31.1	35.1	32.3	30.1

Samples A-E were compared with commercially available un-lined cold packs from Medlogix Inc., P.O. Box 2157, Chester, Va. 23831 (product code 10-01) (Standards A-E). The lots of un-lined commercially available code packs were comprised of urea and water. Standards A-E were activated by squeezing then shaking 10 times. The Standards were folded and inserted into 16 oz Styrofoam cups. The ambient temperature, 68.7° F., was recorded and thermocouples were placed in the fold of each Standard about one inch from the bottom of the cups. Temperature readings were recorded once a minute with the last recording made after 30 minutes. Each Standard was reshaken after a two minute elapsed time. The results are shown in Table II below:

TABLE II

Time (min)	Standard A	Standard B	Standard C	Standard D	Standard E
1	67.8	67.8	67.8	67.8	67.8
2	53.3	54.3	55.9	50.2	57.5
3	52.9	53.4	54.5	49.1	53.2
4	52.3	44.9	51.3	48.4	42.4
5	45.1	44.5	50.7	52.2	38.1
6	41.7	44.7	51.2	52.6	37.7
7	41.2	45.3	51.1	52.7	37.7
8	41.5	45.3	51.3	52.9	38.0
9	42.5	45.4	51.7	52.3	38.2
10	42.5	45.4	51.1	52.0	38.5
11	43.3	45.6	51.3	52.1	38.8
12	45.2	45.7	51.5	52.3	38.9

TABLE II-continued

Time (min)	Standard A	Standard B	Standard C	Standard D	Standard E
13	46.1	45.7	51.6	51.7	39.2
14	46.5	45.7	51.6	51.3	39.5
15	47.0	46.1	51.6	51.4	39.9
16	47.8	46.0	51.6	51.7	40.1
17	47.8	46.1	51.5	51.9	40.3
18	47.7	46.7	51.0	51.7	40.3
19	47.1	46.7	50.3	51.7	40.5
20	47.3	46.7	50.9	51.5	40.9
21	47.3	46.7	50.4	51.7	41.1
22	47.2	46.8	51.3	51.7	41.3
23	47.5	47.4	51.3	51.8	41.4
24	47.6	47.5	51.8	52.0	41.7
25	47.7	47.6	52.0	52.1	42.4
26	47.9	47.7	52.1	52.1	42.3
27	48.1	47.9	52.1	52.3	42.3
28	48.1	48.0	52.3	52.1	42.9
29	48.4	48.1	52.3	52.5	43.1
30	48.6	48.5	52.4	51.9	43.3

The standards were compared with the cooling elements by comparing the average temperatures at each time. The results are shown in Table III, below.

TABLE III

Time (min)	Excel Series 1	Medlogix Series 2
1	68.7	67.8
2	31.46	54.24
3	27.98	52.62
4	29.16	47.86
5	27.14	46.12
6	27.24	45.58
7	27.86	45.6
8	27.52	45.8
9	27.52	46.02
10	27.76	45.9
11	27.82	46.22
12	28.26	46.72
13	28.8	46.86
14	28.98	46.92
15	29.04	47.2
16	29.52	47.44
17	29.68	47.52
18	30.14	47.48
19	30.5	47.26
20	30.76	47.46
11	31.04	47.44
12	31.4	47.66
13	31.78	47.88
14	32.02	48.12
15	32.3	48.36
16	32.56	48.42
17	32.92	48.54
18	33.18	48.68
19	34.06	48.88
20	33.72	48.94

As shown in FIG. 5, the lined cooling element 52 (labeled as Series 1) surprisingly reached an average temperature of 31.46° F. within one minute of being activated (as shown in FIG. 5 at minute 2). The cooling element continues to cool to an average low of 27.14° F. within 4 minutes of activation and remains under 35° F. for at least 30 minutes. By contrast, the control cold packs by Medlogix (FIG. 5, Series 2), even without a lining layer, do not achieve the desired average temperature within a minute of activation. Notably, the Medlogix cold packs, as shown in Series 2, did not reach the desired temperature, but remain at an average of between 45° F. and 50° F.

The cooling element 52 may also be used without the cooling collar 10 to treat pain or to impart selective brain

cooling via the carotid arteries when head and neck injury are not suspected. In this embodiment, shown in FIG. 6, the cooling element may be used in a neck band configuration that comprises a cooling element 52 and a left wing 62 and a right wing 64 attached to each end of the cooling element. The cooling pack 52 may be activated and placed over the patient's carotid arteries, with the wings 62, 64 may be wrapped around the patient's neck and attached to one another in the posterior of the neck with a suitable attachment mechanism, such as a hook and loop fastener (not shown).

In another embodiment, the cooling element 52 may include one or more endothermic packs, such as those containing compartments of ammonium nitrate and water separated by rupturable membranes. In this embodiment, deforming the cooling elements 52 so as to apply differential pressure between the compartments or to otherwise break the membrane can activate such cooling elements 52.

In use, the cervical immobilization collar 10 is placed around a patient's neck, and the cooling element 52 is activated and placed in the anterior opening 28. In one embodiment, the securing member 30 may be placed over anterior opening 28, securing the cooling element 52 between the securing member 30 and the patient's neck. In another embodiment, the collar 10 may not include a securing member 30. In this embodiment, the substantially annular support structure 12 itself is capable of securing one or more cooling elements 52 between the support structure 12 and the patient's neck.

In either embodiment, the cooling element 52 will generally overlie the carotid arteries of the patient's neck and function as a heat extractor for withdrawing heat from blood flowing through the patient's carotid arteries. Preferably, the cooling element 52 conforms to the particularities of individual patient's necks, thereby maximizing skin contact area for more efficiently withdrawing heat from neck tissues adjacent to the carotid arteries. In one embodiment, the cooling element 52 conforms to the patient's neck by using pressure members 56 mounted on a body-facing surface of the securing member 30. In another embodiment, the cooling element 52 conforms to the patient's neck because of the pressure applied by the annular support structure 12 when securely fastened around the patient's neck.

As shown in FIG. 7, in one embodiment the securing member 30 may have a body-facing surface and an outward-facing surface (shown in FIG. 2). As shown, the body-facing surface may include two spaced-apart, pyramid-shaped pressure members 56 that extend toward the user. The pressure members 56 may be formed of other shapes, including blocks, tubes, or any other suitable shape extends toward the patient's neck when the securing member 30 is placed over the anterior opening. The pressure members 56 are placed on the body-facing surface in a position that, when the collar 10 is in use, exerts pressure on the cooling element 52 to maximize skin contact in the carotid artery area. The pressure members 56 may be integrally formed with the body-facing surface of the securing member 30 or may be attached to the body-facing surface of the securing member 30 by suitable means, including an adhesive. Alternatively, the pressure member 56 may be integrally formed with the securing member 30. The pressure members 56 may be made of foam, plastic, or other suitable material. In one embodiment, the pressure members 56 may be made of a 2.8 lb. density open cell urethane foam. The pressure members 56 should be formed so that the pressure exerted on the patient's carotid arteries does not block the patient's airway.

As shown in FIG. 7, a foam layer 58 lines the body-facing surface of the substantially annular support structure 12 to

provide a better fit with the patient's neck. The foam layer may be formed of an open or closed cell foam, or other suitable material. In this embodiment, the substantially annular support structure **12** and the foam layer **58** include a rear, rectangular opening **60** within posterior portion **18** to provide access to the rear of the patient's neck in case there is a need for additional medical procedures. In an alternative embodiment, there is no opening in the posterior portion **18** of the device.

It is also contemplated that the cervical immobilization collar **10** may incorporate a sensor (not shown) mounted in the vicinity of one of the patient's carotid triangle for monitoring one or more circulatory parameters such as arterial oxygen saturation, heart rate, blood pressure, and blood temperature. For positioning the sensor in direct contact with the patient's skin, a portion of the cooling element may need to be reshaped or displaced. A recording device (not shown) can be located elsewhere inside or outside the collar for recording information collected by the sensors. Other sensors can be mounted elsewhere in the collar for monitoring various body parameters, including body temperature, or for monitoring performance of the immobilization collar itself. For example, a temperature gauge, such as a thermochromic strip, can be used for monitoring the temperature of the collar or the cooling element.

A display (not shown) may be placed on the outside surface of the anterior portion of the same cervical immobilization collar. The display can be used for monitoring the circulatory data collected by the sensor as well as other data collected by other sensors mounted in the collar. A communications port (not shown) can also be formed in the collar for transferring data from the one or more sensors to an external device.

The cervical immobilization collar makes possible a new protocol for treating patients, including patients suffering from pain, head trauma, heart attack, ischemic attack, headache, epilepsy, heat stroke, concussion, or similar conditions. It is envisioned that the protocol may be employed by emergency medical technicians or at hospitals, for home use, by athletic trainers, or the like. The treatment centers on installing a cervical immobilization collar around a patient's neck having facility for limiting rotation and compaction of the patient's cervical vertebrae and using the cooling element with the collar to impart selective cooling of the brain via the carotid arteries. The protocol uses vasodilatation of the patient's carotid arteries to evoke selective central core brain cooling and mild hypothermia, as opposed to systemic cooling of the body. As opposed to smaller vessels of the body, which respond by constricting when cold is applied to the skin, the larger blood vessels of the body appear to respond by dilating, allowing increased cooled blood to circulate to the brain from the carotid arteries.

The protocol may include determining the size of collar **10** that the patient requires. Available sizes include conventional no neck, short, regular, and tall cervical immobilization collars. The collar **10** is then applied to the patient and the securing member **30** is opened. The cooling element **52** is then activated by breaking the liquid filled packet and shaking the cooling element **52** for about 15 to about 20 seconds. The cooling element **52** is then placed in the anterior opening **28** in the frame of the substantially annular support structure **12** and may be secured to the patient's neck by placing the securing member **30** substantially over the anterior opening **28**. The cooling element **52** is in thermal transcutaneous communication with at least one of the patient's carotid arteries through an anterior portion of the patient's neck, thus initiating a flow of heat from the one or more carotid arteries through the anterior portion of the patient's neck to the cooling element

and the reducing temperature of the patient's brain without inducing systemic hypothermia.

The cooling element **52** should be left in place for approximately 20, but no more than 30 minutes, at which time the first cooling element should be removed and a new cooling element activated and placed within the collar as described above. This protocol may be repeated as needed.

The protocol can also include monitoring one or more parameters related to circulatory performance of the patient through one or more sensors carried by the immobilization collar. The monitored parameters can include oxygen saturation, pulse rate, blood pressure, or blood temperature. Sensors can also be used to monitor the thermal performance of the cooling element. The protocol of claim can also include measuring a pulse rate of the patient manually by temporarily displacing the cooling element from an opening in the collar over the patient's carotid triangle.

Although the invention has been described with respect to a limited number of embodiments, many more variations will be readily apparent to those of skill in the art in accordance with the overall teaching and scope of this invention. For example, the cooling elements could be mounted on both the anterior and posterior portions of the cervical immobilization collar to extract heat from larger portions of the patients' necks. The cooling of both carotid arteries is generally preferred, but the cooling elements could also be fashioned for cooling just one of the carotid arteries, leaving the other carotid artery exposed for other purposes.

The invention claimed is:

1. A method for selective cooling of the brain of a patient comprising the steps of:

providing a cervical immobilization collar, wherein the cervical immobilization collar comprises a substantially annular support structure having an extended axial length, an anterior opening that extends across a majority of an anterior portion of the annular support structure, and a securing member capable of substantially covering the anterior opening;

applying the cervical immobilization collar to the patient, wherein the anterior opening is capable of exposing both carotid artery regions and a trachea region of the patient; placing a first cooling element within the anterior opening of the substantially annular support structure; and securing the first cooling element within the anterior opening.

2. The method of claim **1**, wherein the securing member includes at least one pressure member capable of imparting pressure against the first cooling element.

3. The method of claim **1**, wherein the method further includes:

replacing the first cooling element with a second cooling element within about 15 to about 30 minutes of the time the first cooling element was placed within the anterior opening.

4. The method of claim **1**, wherein the immobilization collar further comprises at least two cheek support structures having an extended vertical length.

5. The method of claim **1**, wherein the securing member comprises a door with a first edge portion and second edge portion, wherein the first edge portion of the door is attached to the substantially annular support structure at a first edge portion of the anterior opening with a fastening mechanism.

6. The method of claim **1**, wherein the method further includes providing a sensor on the annular support structure of the cervical immobilization collar.

11

7. The method of claim 6, wherein the method further includes monitoring the sensor to assess a health-related parameter of the patient.

8. The method of claim 7, wherein the health-related parameter includes oxygen saturation, pulse rate, blood pressure, and blood temperature.

9. The method of claim 7, wherein the health-related parameter includes thermal performance of the first cooling element.

10. The method of claim 1, wherein the method further includes the step of measuring a pulse rate of the patient manually by temporarily displacing the first cooling element from the anterior opening of the cervical immobilization collar.

11. A method for selectively cooling the brain of a patient comprising the steps of:

providing a cervical immobilization collar comprising a substantially annular support structure having an extended axial length and an anterior opening that extends across a majority of an anterior portion of the annular support structure, wherein the anterior opening is configured to expose both carotid artery regions and a trachea region of the patient;

applying the cervical immobilization collar to the patient; providing at least one cooling element,

placing the at least one cooling element within the anterior opening of the substantially annular support structure; and

securing the at least one first cooling element within the anterior opening; wherein the cervical immobilization collar is capable of securing the at least one cooling element within the anterior opening.

12. The method of claim 11, wherein the cervical immobilization collar is capable of securing the at least one cooling element within the anterior opening by applying pressure to the at least one cooling element so that the at least one cooling element selectively removes heat from at least one of the patient's carotid arteries.

12

13. The method of claim 12, wherein the method further includes providing a second cooling element, wherein the cervical immobilization collar is capable of securing the at least one cooling element and the second cooling element within the anterior opening by applying pressure to the at least one cooling element and the second cooling element so that the at least one cooling element and the second cooling element selectively remove heat from the patient's carotid arteries.

14. The method of claim 12, wherein the method further includes:

replacing the at least one cooling element with a second cooling element within about 15 to about 30 minutes of the time the at least one cooling element was placed within the anterior opening.

15. The method of claim 11, wherein the cervical immobilization collar is capable of securing the at least one cooling element within the anterior opening with a securing member capable of substantially covering the anterior opening.

16. The method of claim 11, wherein the securing member includes at least one pressure member capable of imparting pressure against the at least one first cooling element.

17. The method of claim 11, wherein the method further includes providing a sensor on the annular support structure of the cervical immobilization collar.

18. The method of claim 17, wherein the method further includes monitoring the sensor to assess a health-related parameter of the patient.

19. The method of claim 18, wherein the health-related parameter includes oxygen saturation, pulse rate, blood pressure, and blood temperature.

20. The method of claim 18, wherein the health-related parameter includes thermal performance of the cooling element.

* * * * *